REMARKS

Claims 1-16, 20-22, 38, 39, 68 and 90 were pending in the subject application. By this Amendment applicant has canceled claims 8-11, 20, 38, 39, 68, and 90 without prejudice or disclaimer, and added new claims 98-106. Accordingly, upon entry of this Amendment, claims 1-7, 12-16, 21-22, and 98-106 will be pending and under examination.

Applicant maintains that new claims 98-106 are fully supported by the specification as filed. Support for new claims 98-100 may be found *inter alia* in the specification as originally filed on page 16, lines 17-22. Support for new claims 101-106 may be found *inter alia* in the specification as originally filed on page 16, line 28 through page 18, line 37. Accordingly, applicant respectfully requests that the amendment be entered.

Restriction Requirement Under 35 U.S.C. §121

In the July 9, 2002 Office Action, the Examiner to whom the subject application is assigned stated that restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-11, 16, 20 and 22, drawn to nucleic acid compositions encoding a rodent (mouse or rat) TREX, such as the nucleic acid sequence of SEQ ID NO:1, which encodes the TREX of SEQ ID NO:2, and vector encoding the nucleic acid sequence of TREX;

II. Claims 1-7, 12-16, 21 and 22, drawn to nucleic acid compositions encoding a human TREX, such as the nucleic acid sequence of SEQ ID NO:3, which encodes the TREX of SEQ ID NO:4, and vector

encoding the nucleic acid sequence of TREX;

III. Claim 38, drawn to the protein comprising the amino acid sequence set forth in Figure 7(B) (the specification teaches on page 10 that the protein is mouse TREX from SEQ ID NO:2);

IV. Claim 39, drawn to the protein comprising the amino acid sequence set forth in Figure 8(B) (the specification teaches on page 10 that the protein is human TREX from SEQ ID NO:4);

V. Claim 68, drawn to methods of screening for chemical compound inhibitors of TREX; and

VI. Claim 90, drawn to methods of probing for TREX in a sample from a subject having cancer as a d
cancer.

The Examiner noted the following in regard to Groups III and IV. Groups III and IV were grouped above as drawn to protein compounds since the preamble of claims 38 and 39 were drawn to proteins comprising amino acid sequences. However, there is typographical error in claims 38 and 39 since the claims recite the proteins in Figures 7A and 8A, but the sequences in these figures are actually nucleic acid sequences. It has been assumed that Applicant intended to claim the corresponding protein sequences in Figures 7B and 8B. If this assumption was made in error, and Applicant intended to claim the nucleic acid sequences in Figures 7A and 8A in claims 38 and 39, respectively, these

claims will be rejoined with Groups I and II upon clarification of this point. The Examiner requested Applicant to reply to the instant Official Action with an amendment to claims 38 and 39 so that the intended subject matter is clear.

The Examiner alleged that the inventions are distinct, each from the other because of the following reasons.

> Groups I and II, drawn to nucleic acids, are distinct from Groups III and IV, drawn to proteins. These inventions are distinct because they have different chemical, physical, and functional properties as evidenced by divergent classification, process of making and process of using. For instance, nucleic acid sequences are made of polynucleotides and are found in either single or double strands in a helix orientation and composed of either deoxy-ribonucleotides or ribonucleotides. In the genome, the deoxy-ribonucleotides function to encode messenger RNA, the intermediate agent in protein expression, which is composed of ribonucleotides. Nucleic acids have phosphate backbones that are distinct from the backbones of proteins composed of amino bonds. The nucleic acids of Groups I and II are capable of separate manufacture, use or sale as claimed, and are patentable (novel and unobvious) over the proteins of Groups III and IV (though they may each be unpatentable because of the prior art).
>
> Group I drawn to nucleic acid sequences encoding TREX from rodent (SEQ ID NO:1) is distinct from Group II drawn to nucleic acid sequences encoding TREX from human (SEQ ID

NO:3). The rodent and human TREX sequences in Group I and Group II are restricted from each other because each sequence is patentably distinct as per MPEP 803.04 which states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq." It has been determined that 1(ONE) unique nucleic acid sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Thus Group I is restricted from Group II based on their inclusion of patentably distinct TREX nucleic acid sequences.

Group III drawn to the protein sequence encoding TREX from Figure 7B is distinct from Group IV drawn to protein sequence encoding TREX from Figure 8B. The protein TREX sequences in Group III and Group IV are restricted from each other because each protein sequence is patentably distinct as per MPEP 803.04 (above), for the same reasons that nucleic acid sequences are distinct, *i.e.* the sequence of one protein sequence is capable of separate manufacture, use or sale, and is

patentable (novel and unobvious) over another protein sequence (though they may each be unpatentable because of the prior art). It has been determined that 1(ONE) unique protein sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Thus Group III is restricted from Group IV based on their inclusion of patentably distinct TREX protein sequences.

Any of Inventions I-IV and Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the TREX nucleic acid and protein products of Groups I-IV may be used in diagnostic methods for detection of the TREX in relation to a physiological condition, that does not require screening for a novel inhibitor of TREX as claimed in the methods of Group V.

Any of Inventions I-IV and Invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced

with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the TREX nucleic acid and protein products of Groups I-V maybe used in a method of screening for an agonist or antagonist of TREX, that does not require detection of TREX in relation to a physiological condition.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The Invention of Group V is drawn to methods of screening for chemical compound inhibitors of TREX. The Invention of Group VI is drawn to methods of diagnosing cancer via probe detection of TREX sequences after restriction digestion of DNA from a patient having cancer. The methods of screening for novel compounds in Group V thus have different functions than the methods of diagnosis of cancer via detection of TREX in a patient claimed in Group VI.

The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification and recognized divergent subject matter, and the search required for each of Group I, II, III, IV, V or VI is not required for the other Groups, restriction for examination purposes as indicated is proper.

The Examiner advised applicant that the reply to this requirement to be

complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. §1.143).

In response to this restriction requirement, applicant hereby elects, with traverse, to prosecute the invention identified by the Examiner as Group II, i.e., claims 1-7, 12-16, 21 and 22, drawn to nucleic acid compositions encoding a human TREX, such as the nucleic acid sequence of SEQ ID NO:3, which encodes the TREX of SEQ ID NO:4, and vector encoding the nucleic acid sequence of TREX. Applicant maintains that new claims 98-106 are drawn to the invention of Group II.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction requirement be withdrawn in view of the fact that the claims of the Groups I-VI are not independent.

Under M.P.E.P. §802.01, "independent" means "there is no disclosed relationship between the ... subjects disclosed, that is, they are unconnected in design, operation, or effect... ." The claims of Groups I-VI are related in that they are drawn to nucleic acid encoding TREX, TREX proteins, methods of screening for in TREX, and methods for diagnosing cancer which comprise detecting genetic alterations in the nucleic acid encoding TREX. In particular, Groups I and II are both directed to nucleic acid encoding TREX, and Groups III and IV are both directed to TREX proteins.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject

application because the groups are not independent under M.P.E.P. §802.01.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the inventions must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

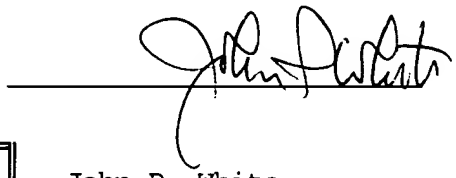
Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to any of Groups I-VI would necessarily identify art for another Group. Since there is no serious burden on the Examiner to examine Groups I-VI in the subject application, the Examiner must examine the entire application on the merits.

Accordingly, in view of the preceding remarks, applicant respectfully requests that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if a fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicant
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

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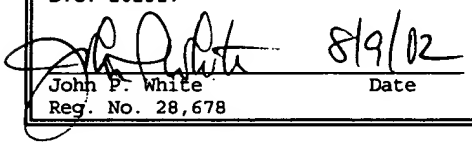

8/9/02
John P. White Date
Reg. No. 28,678